**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF OHIO**
**WESTERN DIVISION**

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| **SHERRY COX, et al.**<br><br>Plaintiffs,<br>**v.**<br><br>**METABOLIFE INTERNATIONAL, INC.**<br><br>Defendant. | **CIVIL ACTION NO. C-1-01-643**<br><br>**JUDGE SANDRA S. BECKWITH**<br>**Magistrate Timothy S. Hogan** |

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| **BARBARA J. BRADLEY**<br><br>Plaintiff,<br>**v.**<br><br>**METABOLIFE INTERNATIONAL, INC.**<br><br>Defendant. | **CIVIL ACTION NO. C-1-02-809**<br><br>**JUDGE SANDRA S. BECKWITH**<br>**Magistrate Timothy S. Hogan** |

**DEFENDANT METABOLIFE INTERNATIONAL, INC.'S OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE DEFENDANT'S EXPERT WITNESS TESTIMONY**

NOW COMES Defendant METABOLIFE INTERNATIONAL, INC., and for its Opposition to Plaintiffs' Motion to Exclude Defendant's Expert Witness Testimony, states that Plaintiffs' have brazenly misrepresented the testimony and basis for the opinions of Defendant's experts, who meet and exceed the requirements of Federal Rules of Evidence 702, 703 and the standard set forth by *Daubert* for admissibility. The basis for this Opposition is more fully set forth in the following Memorandum in Support, which is attached hereto and incorporated by reference herein.

Respectfully submitted,

**Sutter, O'Connell, Mannion & Farchione Co. L.P.A.**

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**MEMORANDUM IN SUPPORT OF DEFENDANT METABOLIFE INTERNATIONAL, INC.'S OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE DEFENDANT'S EXPERT WITNESS TESTIMONY**

## I. Introduction

On September 12, 2003, Plaintiffs moved this Court to exclude the opinions of three of Defendant's experts in the fields of epidemiology, pharmacology and neurology. As demonstrated below, these experts must be allowed to render their opinions in the two instant matters since they not only meet, but exceed the standards set forth by the Federal Rules of Evidence 702 and 703, and the Supreme Court's requirements set forth under *Daubert*.

## II. Law & Argument

### A. Pursuant to Federal Rules of Evidence 702 and 703, as well as the United States Supreme Court decision in *Daubert v. Merrell Dow Pharm., Inc.*, Defendant's expert testimony properly meets the requirements for admissibility as a matter of law.

The Sixth Circuit has long required judges to give a hard look and carefully assess the scientific conclusions and reasoning of experts because jurors are often overly impressed by conclusory opinions of scientific experts paid by a party. *Turpin v. Merrell Dow Pharm., Inc*. 959 F. 2d 1349 (6th Cir. 1992). Federal Rule of Evidence 702 "imposes a special obligation upon a trial judge to 'insure that any and all scientific testimony . . . is not only relevant, but reliable.'" *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 119 S. Ct. 1167, 1174, 143 L. Ed 2d 238 (1999), *quoting Daubert*, 509 U.S. at 589, 113 S. Ct. 2786. "The potential for exaggeration…. is present and may be impossible to discover without close inspection and careful consideration of the record." *Turpin, supra* at 1353.

An expert witness may testify if his opinion or testimony will aid the trier of fact in search of the truth. *South Union, Ltd. v. George Parker & Assoc., AIA, Inc.* (1985), 504 N.E.2d 1131, 1138. The relevant Federal Rules of Evidence on the admission of expert testimony are as follows:

> Rule 702. Testimony by Experts
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> If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.
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> Rule 703. Bases of Opinion Testimony by Experts
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> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted.

All preliminary questions concerning the qualifications of persons to be witnesses are to be determined by the trial court. *Wagenheim v. Alexander Grant & Co.* (1983), 482 N.E.2d 955, paragraph fifteen of the syllabus. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.* (1993), 509 U.S. 5879, the United States Supreme Court held that trial judges were required to make an initial determination "of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Thus, the initial qualification or competency of a witness to testify as an expert

or to give his opinions on a particular subject rests with the trial court. *Fulton v. Aszman* (1982), 446 N.E.2d 803, paragraph one of the syllabus.

However, the gatekeeping function of the trial court is not to choose between conflicting opinions, or to analyze and study the science in question in order to reach its own conclusions. Ultimately, it is the role of the trial court to ensure the reliability and relevancy of expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152. "It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.*

**B. Craig Molgaard, Ph.D., M.P.H.**

Dr. Craig Allen Molgaard is the Chair and Professor of the Department of Preventive Medicine and Public Health for the University of Kansas School of Medicine, where he has been for the past seven years. After graduating from Iowa State University in 1974 with a B.A. in Anthropology, he went on to complete his Ph.D. in Anthropology in 1979 and M.P.H. in Epidemiology in 1982 from the University of California, Berkeley. Dr. Molgaard specializes in the areas of cardiovascular epidemiology, in which he completed an NIH postdoctoral fellowship, and neuroepidemiology, the epidemiology of neurological disorders, such as strokes. In particular, Dr. Molgaard has edited a book in the area of neuroepidemiology, has been published in that field, and was on the editorial board of a journal called "Neuroepidemiology." In total, he has over 120 publications and has received numerous grants and contracts. (See Exhibit A attached, Curriculum Vitae of Craig A. Molgaard, Ph.D., M.P.H. for a complete listing of his education, training and experience, including a list of publications and grants.)

Dr. Molgaard's expertise in the field of epidemiology, neuroepidemiology and cardiovascular epidemiology is undeniable. As discussed in Defendant's Motion for Summary

Judgment and supporting exhibits, Dr. Molgaard has formulated his opinions in this case based on his extensive research and experience in the field of epidemiology, a review of the available scientific literature on the subject of ephedrine, ephedra with or without caffeine, and hemorrhagic stroke, a review of an epidemiologic study and controlled clinical trials, treatises, textbooks, and a variety of other sources.[1]

Plaintiffs have attempted first to disqualify his opinions because he is not a medical doctor. What they have failed to grasp is the concept of epidemiology, and the importance of this field in understanding the cause of injury and disease in a population. Epidemiology can be defined as, "the study of distribution of disease and injury in a population, and the determinants of that distribution. *** **Elucidation of the cause of injury and disease is the ultimate goal of the science of epidemiology.** This in turn leads to the development of interventions at the population level to prevent disease and injury."[2] Unlike clinicians, who may rely on anecdotal evidence and unfounded tradition, an epidemiologist looks at evidence-based medicine to determine whether there is in fact a conclusion that may be drawn to establish causation. In other words, epidemiologists rely on a much more solid body of evidence for their decisions. (Deposition of Molgaard, p. 83).

Plaintiffs also attempted to discredit Dr. Molgaard by stating that he has not relied on certain evidence, but then list anecdotal, unreliable sources of information. For example, Plaintiffs throughout this litigation have held out case reports and adverse event reports in support of their position that establish ephedra causes strokes. This is not true. Plaintiffs have conveniently failed to disclose the GAO's conclusions in the March, 2003 Report that states:

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[1] See Defendant's Motion for Summary Judgment, Exhibit F: Affidavit of Craig A. Molgaard, Materials Reviewed.

[2] *Epidemiologic Assessment of health Line Reports About a Dietary Supplement*, Craig A. Molgaard, PhD, MPH, August 2002, p. 34 (citations omitted, emphasis added).

> **Because of the inherent limitations of adverse event reports and the incomplete nature of these call records, we cannot establish that the reported adverse events were caused by the use of Metabolife 356.**

(See *Dietary Supplements: Review of Health-Related Call Records for Users of Metabolife 356,* GAO Report to the Chairman, Subcommittee on Wellness and Human Rights, committee on Government Reform, House of Representative, March 2003.)

In fact, Plaintiffs purport in their Memorandum in Support that the GAO Report of July, 2003, outdates its earlier statements. Again, this is not true. The GAO still holds the position that the FDA has not established a causal link between the ingestion of ephedrine alkaloids and the occurrence of particular adverse events.[3] The July, 2003 report is simply a summary of FDA's investigation on ephedra to date, and does not assert any new recommendations or findings of the General Accounting Office. Simply because Plaintiffs' counsel states that case reports and adverse event reports "provide substantial and reliable evidence" does not make it a reality. (Plaintiffs' Memorandum in Support, p. 2.) These are words artfully chosen by Plaintiffs' counsel to argue their position, and do not necessarily represent the sentiment held by the scientific community.

Plaintiffs also comment that Dr. Molgaard ignores published epidemiological studies that concluded ephedra use in doses exceeding 32mg per day is associated with an increased risk of hemorrhagic stroke.[4] In fact, in the one study referred to, the authors state that their results do not indicate an association between the use of ephedra-containing products and increased risk for hemorrhagic stroke, but that there *may* be an association with the use of more than 32mg/day

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[3] *Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedra* Alkaloids, GAO Report to the Chairman and Ranking Minority Member, Committee on Science, House of Representatives, July 1999, p. 24.

[4] Despite the plural reference to "studies," Plaintiffs only cite to one paper, which is then criticized by Dr. Molgaard as explained later in this brief.

based on the analysis of PPA and uncontrolled case reports. Plaintiffs also fail to address Dr. Molgaard's criticism of this paper:

> Q: And in that study the authors concluded that there was evidence suggesting an increased relative risk based upon a small data available, as you previously noted, in people having subarachnoid and intracranial hemorrhages after taking more than 32 milligrams of ephedra-containing products per day?
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> A: They say that in that paper, but the data do not support that. And what they had was they had an elevated point estimate; but, when they ran the confidence interval on the point estimate for beyond 32 milligrams, it was not statistically significant. So, what they had basically was a negative study, but they had this one point estimate that was elevated up and so then they tried to argue that that was an important finding. But, once again, you have to give the authors their due, they were using a data system that was not designed to do research on ephedra, per se, they were doing a secondary analysis on the system the Yale had put together to look at PPA.
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> ***
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> Q: [S]o, is it Morgenstern that you believe is inconclusive?
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> A: Yes, I do.

(Deposition of Molgaard, p. 78.) This is precisely the type of critical analysis that is required by Dr. Molgaard's field, and which Plaintiffs' conveniently ignore.[5]

Plaintiffs' attack on Dr. Molgaard's testimony and opinions is filled with inaccuracies and misstatements of evidence. His qualifications, methodology and opinions withstand the admissibility requirements set forth by the Federal Rules of Evidence and *Daubert*. Whether there is scientific, epidemiological evidence that ephedra can cause a hemorrhagic stroke is relevant and his opinions, based on his extensive research and analysis of these issues, would

[5] It should be noted that Plaintiffs have not even retained an expert in the field of epidemiology.

undoubtedly be helpful to the trier of fact. For all these reasons, Dr. Molgaard is qualified to give expert opinions on the issues of epidemiology and causation in the instant matters.

**C. Ronald Millard, Ph.D.**

In a similar fashion to the shotgun approach they took with Dr. Molgaard, Plaintiffs attempt to disqualify the opinions of Defendant's expert pharmacologist, Dr. Ronald Wesley Millard, Ph.D. Dr. Millard graduated from Tufts University with a B.S. in Chemistry and Biology in 1963, obtained his Ph.D. from Boston University in Physiology in 1969, with an emphasis on the physiology of the cardiovascular and autonomic nervous systems, including the actions of sympathomimetic drugs in the heart. He was formerly the Assistant Professor of Physiology and Internal medicine at Harvard University Medical School, and Assistant Professor of Medical Sciences-Physiology and Biophysics at Brown University Program in Medicine. Over his career, Dr. Millard has published over 100 scientific articles and book chapters in his field. For the past 25 years, he has held the primary faculty position in Pharmacology and Cell Biophysics at the University of Cincinnati, and has concurrent positions at the College of Medicine and Engineering in Internal Medicine-Cardiology, Radiology-Nuclear medicine, and Materials Science Engineering. (See Exhibit B attached, Curriculum Vitae of Ronald W. Millard, Ph.D., for a complete listing of his education, training and experience.)

In formulating his opinions, Dr. Millard relies on his education, research and experience on the actions of sympathomimetic amines on the heart and cardiovascular system, his review of the pharmacology and toxicology of sympathomimetic amines, especially ephedrine and ephedrine alkaloids, and of methylxanthines, especially caffeine. Moreover, Dr. Millard has designed and supervised for over 10 years a laboratory course for medical students to illustrate

the effect of placebo and sympathomimetic drugs (including ephedrine) on the heart rate and heart contractile performance.[6]

Dr. Millard's qualifications in the field of pharmacology are without question. Rather, Plaintiffs question his reliance on certain studies and review of the available scientific literature. Again, their recitation of the evidence is misleading. For instance, Plaintiffs think that simply because Dr. Millard did not agree that ephedra causes "very large changes" in blood pressure in heart rate, is a reason to exclude his opinions. When analyzing the record, Plaintiffs' counsel failed to define what change in blood pressure or heart rate she considers to be "large," on what study she is relying, or any characteristics of the population group to which she is referring. Without any defined variables, Dr. Millard suggested what he would consider to be a significant change in blood pressure or heart rate, and the basis for his reasoning:

> A: I think that the responses that I would consider of biological, potential biological significance – and when I say that I don't want to translate that into necessarily pathological consequence – would be outside and above, sufficiently above the normal range of blood pressures, and if we're talking about heart rate, of heart rate that we experience as humans in our daily lives.
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> And that information depends upon the age that we are, and probably involves aspects of each of our individual genetics and that sort of thing. But on average, numbers are available that represent the average daily ranges of heart rate and blood pressure that exist throughout a 24-hour cycle. And those changes are typically in the range for blood pressure of ten or 20 millimeters of mercury difference from the low points to the high points.
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> And so to have a measurable, and I think – well, I don't know, a measure of interest, I would want to see that they are clearly above that range. And as I said earlier, sustained. Because frequently going back to my own personal laboratory research experience, administrations of drugs that have action on the cardiovascular system typically will be accompanied by adjustments made by the body and the nervous system, by the nervous system and by the hormone system, that tend to oppose, attenuate, normalize, if we're

[6] See Defendant's Motion for Summary Judgment, Exhibit M: Affidavit of Ronald W. Millard, Ph.D.

> talking, focused now on blood pressure and heart rate to the pre-exposed levels relatively rapidly.

(Deposition of Dr. Millard, p. 51-52.) Despite this lengthy explanation, relying on his education and experience, Plaintiffs' counsel discounts his opinion without providing any explanation why.

Plaintiffs also string together other parts of Dr. Millard's deposition, insinuating that based on what Dr. Millard agrees with or disagrees with, his testimony should be excluded. Plaintiffs' counsel also argues that since Dr. Millard "concedes" to certain pieces of information, he should agree with her ultimate conclusion. This is not the test of admissibility and Plaintiffs' assertions are incredulous, spurious, and unconvincing.

Dr. Millard's qualifications, methodology and opinions withstand the admissibility requirements set forth by Federal Rules of Evidence 702, 703 and *Daubert* and his opinions on causation and pharmacology are relevant and substantiated by his extensive research and experience in the field. For all these reasons, Dr. Millard is qualified to give expert opinions on the issues of pharmacology and causation in the instant matters.

**D. Guy Rordorf, M.D.**

Interestingly, Plaintiffs avoided discussing Dr. Guy Rordorf's qualifications. Defendant's third expert that is the subject of this motion is, Guy Rordorf, M.D., is a medical doctor and an Assistant Professor of Neurology at Harvard Medical School and the Associate Director of the Neuroscience Intensive Care Unit at the Massachusetts General Hospital. In this capacity, he cares for nearly 300 patients a year who suffer from stroke. There is no question as to his qualifications or credentials in the field of Neurology.

Plaintiffs only avenue for attacking Dr. Rordorf's opinions is their claim that his testimony is contradictory. This is a blatant mischaracterization. For instance, Plaintiffs suggest that Dr. Rordorf's statement in his affidavit that Linda Beckman did not have an increase in

blood pressure and heart rate associated with her use of ephedrine contradicts his deposition testimony. In fact, throughout the deposition, Dr. Rordorf explains that instances of elevated heart rate and blood pressure were noted, but were when she was experiencing pain. These instances were not considered in evaluating an increase in blood pressure or heart with use of ephedrine, because they were symptoms of pain. As he explained:

> A: All this blood pressure reading were in the setting of pain from headaches. And so as I told you before, we cannot put, nobody should or we cannot put any emphasis on high blood pressure in the setting of pain.

(Deposition of Rordorf, p. 90.) The other point that Plaintiffs attempt to make is whether Ms. Beckman's berry aneurysm was congenital, or developed during the course of her life. Again, Plaintiffs' counsel misrepresents Dr. Rordorf's testimony. As he testified, berry aneurysms are in fact congenital defects, and if they do form later in life, take years to develop and are the result of a congenital weakness in the vessel wall. He never indicates that Ms. Beckman's berry aneurysm formed shortly before her death.

Moreover, the responsibility of this Court is not to evaluate Dr. Rordorf's conclusion, but rather, the methodology used to establish his opinions. *Kumho Tire Co., supra.* Under the Federal Rules of Evidence 702, 703 and *Daubert,* Dr. Rordorf's opinions on causation and neurology are relevant and admissible.

## III. Conclusion

WHEREFORE, Defendant Metabolife International, Inc. respectfully requests this Court DENY Plaintiffs' Motion to Exclude the testimony of Dr. Molgaard, Dr. Millard, and Dr. Rordorf, and allow these experts to render their opinions as set forth by the Federal Rules of Evidence 702 and 703, and the Supreme Court's requirements under *Daubert*.

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of the foregoing was sent by U.S. mail, postage prepaid, this 19th day of September, 2003, to the following:

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